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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 26 and 27, 2000, 8:30 a.m. to 5:30 p.m.

Location: Marriott Washington Center, Ballrooms A through E, 9751 Washington Blvd., Gaithersburg, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6758, e-mail at PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 26, 2000, the committee will discuss new drug application (NDA) 21–200, Zelmac™ (tegaserod), Novartis Pharmaceuticals Corp., for the treatment of abdominal pain and discomfort, bloating and altered bowel function in patients with irritable bowel syndrome who have predominant symptoms of pain, discomfort, and constipation. On June 27, 2000, the committee will discuss risk management of post-marketing adverse events associated with NDA 21–107, Lotronex™ (alosetron) Glaxo Wellcome.

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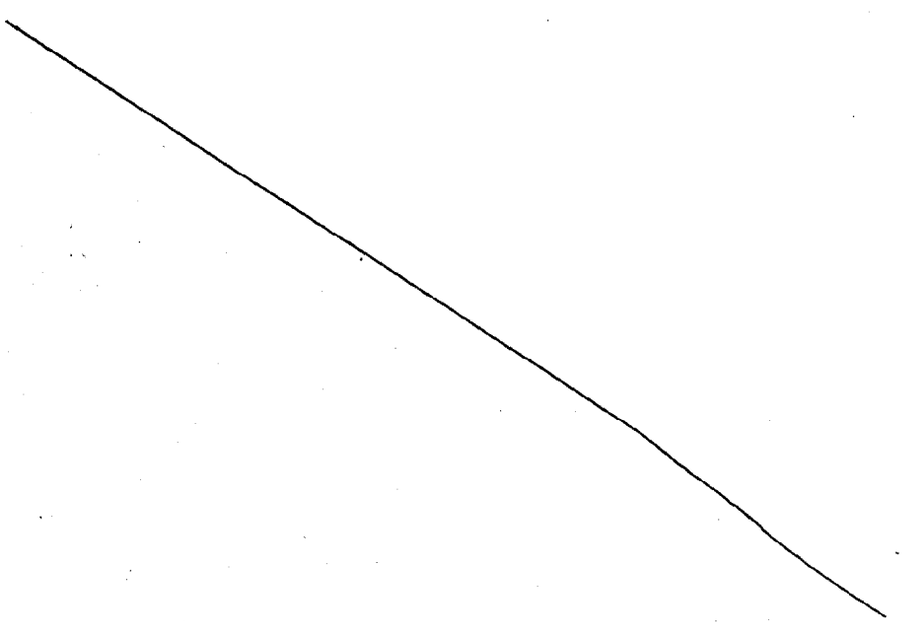
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 19, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 19, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the June 26 and 27, 2000, Gastrointestinal Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Gastrointestinal Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 5, 2000

Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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